# ORIGINAL

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

THIS DOCUMENT RELATES TO:

County of Suffolk v. Abbott Laboratories, Inc., et al.,

E.D.N.Y. Case No. CV-03-229

MDL. NO. 1456

Civil Action No. 01-CV-12257- PBS

Judge Patti Saris

SUFFOLK COUNTY'S OPPOSITION TO THE DEFENDANT-SPECIFIC MEMORANDA IN SUPPORT OF MOTION TO DISMISS

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#### INTRODUCTION

In addition to joining in the consolidated memorandum in support of their motion to dismiss, twenty-one defendants<sup>1</sup> have filed "defendant-specific" memoranda (a) reiterating arguments already raised in the consolidated motion, and (b) asserting fact-intensive arguments and *ipse dixit* that contradict the pleadings, go to the merits of the case, and are wholly improper at the motion to dismiss stage. *Monahan v. Dorchester Counseling Ctr., Inc.*, 961 F.2d 987, 988 (1<sup>st</sup> Cir. 1992)(in considering motions to dismiss, court must take allegations in complaint as true and make all reasonable inferences in favor of plaintiff). Defendants' "specific" arguments fail just as their consolidated arguments do.

One overarching observation. Defendants focus on Rule 9(b). Seven of Suffolk's nine claims do not implicate Rule 9(b). Suffolk's claims for violation of 42 U.S.C. § 1396r-8 (Count II); violation of New York Soc. Serv. L. § 367-a (Count III); violation of 18 N.Y.C.R.R. 515.2(b)(4) and (5) (Count IV); violation of N.Y. Soc. Serv. L. § 145-b (Count V); violation of New York's Unfair and Deceptive Trade Practices Act, General Business Law § 349 (Count VII), breach of contract (Count VI) and unjust enrichment (Count IX) each have independent pleading requirements, which Suffolk has satisfied entirely. *See* Suffolk's Opposition to Defendants' Consolidated Motion to Dismiss ("Suffolk Opp.") at Points II-VIII.. In any event, as set forth herein, Suffolk's pleading completely satisfies Rule 9(b) and this Court's May 13, 2003 ruling respecting particularity.

<sup>&</sup>quot;Defendant Specific" Memoranda were filed by: Abbott Laboratories, Inc., Amgen Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals, Bayer Corporation, Berlex Laboratories, Inc., Biogen, Inc., Eli Lilly and Company, Forest Pharmaceuticals, Inc., MedImmune, Inc., Merck & Co., Inc., Novartis Pharmaceuticals Corporation, Pfizer Inc., Agouron Pharmaceuticals, Inc., Pharmacia Corporation, Purdue Pharma L.P., Reliant Pharmaceuticals, LLC, Sanofi-Synthelabo, Inc., Schering-Plough Corporation, TAP Pharmaceutical Products, Inc., Warrick Pharmaceuticals Corporation, and Wyeth.

Given that many of the "defendant-specific" arguments are, in fact, redundant, Suffolk first addresses those, and then turns to what individual points remain.

#### **RESPONSE TO COMMON ARGUMENTS**

#### A. Suffolk Has Satisfied Rules 9(b) And 8

Nearly every defendant who filed a "defendant specific" brief complains that Suffolk has not satisfied 9(b) particularity for its fraud claims.<sup>2</sup> First, to reiterate, only two Suffolk's nine claims sound in fraud Count I (RICO, 18 U.S.C. § 1962(c) and Count VIII (Common Law Fraud). Second, defendants are incorrect. Suffolk has satisfied Rule 9(b) and this Court's May 13 directive requiring identification of "the specific drug or drugs that were purchased from the defendant [and] the allegedly fraudulent AWP for each drug." *In re Pharm. Industries Average Wholesale Price Litigation*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) ("in re AWP Litigation"). Suffolk has stated a misleading, false and inflated AWP defendant by defendant and drug by drug<sup>3</sup> (AC at ¶ 122-314 and Exhibit A). Suffolk also has alleged that each defendant, routinely and over a period of years, reported these misleading, false and inflated AWPs, or caused them to be reported to non-party publishers such as Blue Book, First Data Bank or Redbook. *Id.* Defendants properly can demand no more at this stage. *See Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347, 354 (D. Mass. 1999)

See Abbott at 2; Amgen at 1; AstraZeneca at 2; Aventis at 2; Bayer at 1; Berlex/Forest/Purdue/Reliant at 2; Biogen at 3; Eli Lilly and Company at 1; MedImmune at 2; Merck & Co. at 1; Novartis at 1; Pfizer and Agouron at 1; Pharmacia Corporation and Pharmacia & Upjohn, Inc. at 1; Sanofi-Synthelabo at 3; Schering-Plough at 1; TAP Pharmaceutical Products at 1; Warrick Pharmaceuticals at 4; and Wyeth at 1.

A number of defendants argue that Suffolk's claims for damages suffered in connection with Covered Drugs as yet unidentified or for which no fraudulent AWP is yet provided should be dismissed. Respectfully, defendants are incorrect. Suffolk's allegations with respect to the pervasiveness of the AWP/Best Price scheme and defendants' complicity therein demonstrates that all of Suffolk's Medicaid pharmacy costs were excessive. AC at ¶¶ 315-317. Moreover, Suffolk satisfies the pleading standards for those of its claims that do not sound in fraud. See Suffolk Opp. at Points II-VIII. In the event the Court seeks further specificity regarding such damages however, Suffolk will seek leave to amend.

(plaintiff must set forth the "who, what, when, where and how" of the alleged fraud).4

And yet they do. A number of defendants complain that Suffolk has not explained why the AWPs are fraudulent, but such a requirement cannot be found in the Court's order, nor in any rule. Such a demand is is particularly inappropriate here given that Suffolk alleges (AC at ¶ 128, 322-331, e.g.) and defendants concede (Con. Mem. at 5, 7) that the facts surrounding defendants' discounting and rebate activities are uniquely within defendants control at this time. Suffolk's preliminary estimates of overcharges based on publicly available data (AC at ¶ 121, 114, e.g.), specifically note that such estimates "are understatements because they do not include the defendants' failures to report Best Price as required by federal and state rebate statutes." AC at ¶ 124, e.g. Accordingly, even if required (and it is not), quantification of the exact extent of defendants' price manipulation simply cannot take place in advance of discovery. Courts do not place a burden to quantify damages or plead detailed facts that are outside the reach of plaintiffs. <sup>5</sup>

Nor can defendants be heard to complain that Suffolk has failed to satisfy Rule 8. To satisfy Rule 8, a party need set forth only "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R.Civ.P.8(a)(2). The purpose of the rule is to provide a party fair notice whether there are sufficient facts alleged upon which relief can be granted. See Analog Devices, Inc. v. Allied Van Lines, Inc., 1996 WL 208463 at \*3 (D.Mass. 1996), citing Wright &

It is worth noting that this particularity argument is not "defendant-specific". It appears also in Defendants' Consolidated Memorandum In Support of the Motion to Dismiss ("Con. Mem.") at pages 35-37. Suffolk responds fully to the point in its opposition to that brief. See Suffolk Opp. at Point IX.

Should the Court request further particularity, discovery -- not dismissal -- would be appropirate. See, e.g., New England Data Servs. Inc. v. Becher, 829 F.2d 286, 290-291 (1st Cir. 1987) (when information is beyond the grasp of the plaintiffs and within the province of defendants, a RICO claim should not be dismissed on a Rule 9(b) basis without first affording plaintiffs additional discovery providing such information).

Miller, 5 Federal Practice & Procedure Sec. 1219 (1969) ("all that is necessary, under Fed. R. Civ. P. 8, "is that the plaintiff set forth sufficient factual allegations to state a claim showing that he is entitled to relief under some viable legal theory.") See also 2 Moore's Federal Practice, Sec.8.04[3] (3d ed. 1999) ("All that is required is that the defendant be on notice as to the claim being asserted against him and the grounds on which it rests."); Conley v. Gibson, 355 U.S.41, 47 (1957) (complaint need only "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests."). Defendants' individual and consolidated briefs are Q.E.D. that they fully understand the claims asserted.

#### B. Alleged Government Knowledge Is Not Grounds For Dismissal

As in their consolidated memorandum, a number of defendants have the temerity to argue that even though they misrepresented and submitted false statements regarding the AWPs and best prices for their drugs, in direct violation of federal and state law, New York State had the means to detect their lies, and, thus, no liability attaches for the misconduct. *See for example*, Abbott at 4; Merck at 3, 5, Schering at 2-3, Warrick at 3-4, and Wyeth at 2-3.

First, the argument is, not surprisingly, made with no authority whatever. Of course, there is nothing in the federal or state Medicaid statutes or regulations to support the notion that a pharmaceutical company may violate these statutory requirements at will, so long as they elsewhere

provide data that might, through a herculean effort<sup>6</sup>, reveal such violations. This Court already has rejected the argument as grounds for dismissal. *In re AWP Litigation*, 263 F. Supp. 2d at 187.

Second, the argument contradicts entirely Suffolk's allegations, controlling at this stage, that Suffolk did not know truth respecting the full amount of defendants' fraudulent reporting of AWPs and failures to report best prices due to defendants' fraudulent concealment, AC at ¶ 98, 322-331. It ignores also that defendants themselves concede that the Best Price data is not disclosed to states. Con. Mem. at 7. Finally, the argument is, at its essence, an affirmative defense raising disputable facts not properly resolved at this state.

#### C. Suffolk's Best Price Allegations Are Sufficiently Particular

Contrary to a number of defendants' arguments<sup>7</sup>, the Suffolk complaint adequately and specifically alleges the Best Price Scheme and defendant's participation in it. AC at ¶ 2, 8, 76-80, 84-93, 124, e.g. Suffolk alleges that, at the heart of this scheme are defendants' unreported discounting of drugs, free samples, and other inducements, both to physicians and other suppliers. AC at ¶ 85. Suffolk alleges that defendants' unreported discounting takes many forms, including targeting "low volume billers," *Id.* at ¶ 86, rebates, educational grants, *Id.* at ¶ 87, and "chargebacks" to wholesalers, *Id.* at ¶ 88. Suffolk alleges that recent government investigations and settlements, including and involving defendants herein, reveal for the first time, defendants failures to comply

Consider Abbott's argument. Abbott says Suffolk could have discovered its statutory violation by performing a reverse calculation using the drugs unit rebate amount to arrive at the Average Manufacturer's Price ("AMP") for the Covered Drugs and then use the AMP information to calculate the true pricing information defendants' should have reported in the first place but did not. Abbott at 4. Suffolk certainly had no obligation to engage in these mathematical gymnastics to discover Abbott's violations. Moreover, even if Suffolk did so, AMP refers to Manufacturer's Price, not Wholesaler's.

See Abbott at 2, Amgen at 4, AstraZeneca at 2, Berlex/Forest/Purdue/Reliant at 3, Biogen at 4, Merck at 3, Novartis at 3, Pharmacia at 3, Sanofi at 4, Schering at 3, TAP at 1, Warrick at 5.

with their rebate requirements.<sup>8</sup> And, Suffolk alleges that Best Price data is uniquely within defendants' control. AC at ¶ 121. Defendants concede Suffolk does not have access to best prices. Con. Mem. at 7. Suffolk goes further and alleges that its damages will be affected by these failures to report Best Prices. See e.g., ¶¶ 127, 128. Under these circumstances, Suffolk's rebate allegations are sufficiently particular. And even if the court accepts defendants' particularities allegations, defendants' argument does not touch Suffolk's seven claims that do not implicate Rule 9(b). See Introduction, supra at 1. See also Suffolk Opp. at points II- VIII.

#### D. Competition Is Irrelevant

Certain defendants seek dismissal on the grounds that because there are no competitors for their drugs, they have no motive to engage in the wrongdoing alleged in Suffolk's complaint. The argument fails. Suffolk alleges motive whether there is competition or not. AC at 8, 68, 84-93, 100, 102, 107. The motive is profit. Defendants fail to report the best prices for their drugs, to avoid having to pay rebates. AC at \$\frac{1}{3}\$ 8. Defendants' rebate obligations have nothing to do with whether a competitor exists. Any defendants who manufacture a Medicaid Covered Drug must report their best price and pay rebates based on that. AC at \$\frac{1}{3}\$ 76-80. Every defendants is motivated to pay as little a rebate as possible. AC at \$\frac{1}{3}\$ 91. Second, Suffolk alleges all defendants discount and market their drugs (which defendants concededly do, see, e.g., Medimmune at 1) competitor or not. Suffolk alleges defendants likewise market the spread to incentivise wholesalers, PBMs and

Suffolk diligently investigated Defendants' conduct, and has found numerous examples of investigation, settlements and convictions arising out of Best Price manipulation by Defendants. See Suffolk's discussion of Abbott (AC at ¶ 130, 131), Astrazeneca (AC at ¶ 150-157), Aventis (AC at ¶ 163), Bayer (AC at ¶ 178-180), Glaxo (AC at ¶ 235-244), Pfizer (AC at ¶ 272-277), Schering (AC at ¶ 294-295), and TAP (AC at ¶ 304).

See Abbott at 3, Medimmune at 1, TAP at 2.

other third party intermediaries or providers to select their product. AC at ¶¶ 322, 325.

Moreover, government investigations and settlements, not to mention defendants' own submissions confirm that defendants report false and misleading AWPs, competitor or not. AC at ¶ 94-99. Why? The reason certainly cannot be resolved on this motion. Similarly, defendants' own submissions make plain that this court cannot determine as a matter of law which drugs have competitors and which do not. For example, Medimmune argues that Synagis has no competitors (Medimmune at 1, 2) but, in fact, Medimmune continues to manufacture and sell Respigam, Synagis' predecessor. Is Respigam a competitor of Synagis? Did Medimmune inflate the Synagis AWP to encourage providers to utilize it instead of the predecessor drug? Clearly, these are question of fact that are not resolvable on a motion to dismiss. 10

Finally, motive is not an element for Suffolk's claims for violation of 42 U.S.C § 1396r-8, N.Y. Soc. Serv. L. § 145-b, New York Soc. Serv. L. § 367-a, General Business Law § 349, 18 N.Y.C.R.R. § 515.2(h)(4) and (5) or breach of contract. See Suffolk Opp. at Points II-IV. Even if this Court accepts defendants' motive-based arguments as grounds for dismissal, which it should not, such are irrelevant entirely to those claims.

### E. Suffolk Properly Includes Multi-Source Drugs In Its Complaint

Abbott says Suffolk alleges no competitors for Depakote and Kaletra. Abbott at 3. It is irrelevant as set forth herein. Even if not, it raises a factual question. A Sept. 17, 2003 New York Times article reported that Lithium, "an old and inexpensive drug", is actually more effective than Depakote. Is Lithium a competitor for Depakote? What drugs compete with Kaletra? Clearly, these are issues of fact not properly resolved at the motion to dismiss stage.

This dispenses also with the argument of certain defendants also argue that there is no incentive to "market the spread" in Medicaid given the distribution channels for covered drugs. But this is a disputed fact. See AC at 100-107. Further, Suffolk alleges and government investigations and settlements confirm that defendants are engaged in this scheme to avoid Medicaid rebates. AC at 8, 170, 237, e.g. The matter cannot be ruled on as a matter of law.

There is no basis to exclude multi-source drugs from the complaint, as certain defendants claim. See e.g., Warrick at 4, Novartis at 2. Multi-source drugs are reimbursed based on AWP just like brand name drugs, whether there is a Federal Upper Limit ("FUL") established or not. See N.Y. Soc. Serv. L. 367-a; 42 C.F.R. 442.332(b). In any event, this is not a "defendant specific" argument, but included in defendants' consolidated motion. See Con. Mem. at 447.332. In the interest of efficiency, Suffolk respectfully refers the Court to Suffolk Opp. at page 7.

# F. Under No Circumstances Should Suffolk's Claims Be Dismissed With Prejudice

A number of defendants assert<sup>12</sup> that Suffolk has not satisfied 9(b), and so its claims should be dismissed with prejudice.<sup>13</sup> Seven of Suffolk's nine claims do not implicate Rule 9(b) and Suffolk has satisfied the independent pleading requirements for those claims. *See* Suffolk Opp. at Points II-VIII. Further, for Suffolk's two claims that do sound in fraud, Suffolk has satisfied 9(b). *See* Point A, *supra*. Finally, the remedy proposed by defendants is a drastic one, which the Court already and expressly refused to adopt when considering the class action pleadings in *In re AWP Litigation*, 263 F. Supp 2d at 194. A similar result is appropriate here should the court find infirmities in Suffolk's complaint.

See Amgen, Ind MTD at 5, Aventis, Ind MTD at 3, Suffolk Only Defendants, Ind MTD at 5, Sanofi, Ind MTD at 5, and Schering, Ind MTD at 4.

<sup>&</sup>lt;sup>13</sup>Amgen is the only defendant that substantively addresses the issue. However, Amgen's cases were in different procedural posture and distinguishable. In each, the court was considering whether to grant leave to amend <u>for a second time</u>, after first giving the plaintiffs leave to amend to cure 9(b) deficiencies. See Taponga v. Egan, 141 F.R.D. 370, 373, 379 (D. Mass 1992) and Hayduk v. Lanna, 775 F.2d 441, 445 (1st Cir. 1985) Here, the Court has never before ruled on the sufficiency of Suffolk's pleading.

#### RESPONSE TO DEFENDANT-SPECIFIC ARGUMENTS

#### A. Abbott Laboratories, Inc.

Suffolk has satisfied the court's and 9(b)'s requirements for its fraud based claims against Abbott. S uffolk alleges that it p aid for three Abbott drugs in 2001, two dosages of Depakote, and Kaletra Softgels. AC at ¶ 23. Suffolk alleges each had a misleading, false and inflated AWP, (id.), that Abbott reported or caused to be reported. AC at ¶ 125. Specifically, \$1.04 for Depakote 250 mg (AC at ¶ 125 & Exhibit A), \$1.92 for Depakote 500 mg (id.), and \$3.91 for Kaletra Softgel. Id. Suffolk's particular Abbott allegations satisfy 9(b) and this Court's May 13 directive.

#### B. Amgen

### 1. Suffolk Has Satisfied the Court's and 9(b)'s Requirements for its Fraud Based Claims Against Amgen

Suffolk alleges that it paid for three Amgen drugs, Neupogen, Epogen, and Enbrel, in 2001. AC at ¶ 25. Suffolk alleges each had a misleading, false and inflated AWP, (id.), that Amgen reported or caused to be reported. AC at ¶ 138. Specifically, \$227.60 for Neupogen Vial 300 MCG/ML, (AC at ¶ 138, and Exhibit A), \$163.33 for Enbrel kit (id.), and \$134.59 for Epogen Vial 10,000 U/ML. Id. Suffolk's particular Amgen allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

### 2. Amgen Misrepresents How Epogen Is Reimbursed Under Medicaid; The Argument Must Be Withdrawn

Amgen tells the courts that Suffolk's claims concerning Epogen should be dismissed because Medicaid reimbursements for Epogen are not based on AWP according to 42 U.S.C. Sec.

1395rr(b)11(B). Amgen at 5. Not so. The statute Amgen cites does not apply to Medicaid reimbursements. It applies to Medicare. In fact, there is no federal or state statute anywhere that says that Medicaid reimbursements for Epogen are based on anything other than AWP. Amgen's argument must be withdrawn.

#### C. AstraZeneca Pharmaceuticals LP.

Suffolk has satisfied the court's and 9(b)'s particularity requirement for its fraud based claims against AstraZeneca. Suffolk alleges that it paid for five AstraZeneca drugs in 2001, 3 dosages of Seroquel, Prilosec and Nexium. AC at ¶ 26. Suffolk alleges each had a misleading, false and inflated AWP, (id.), that AstraZeneca reported or caused to be reported. AC at ¶ 146. Specifically, \$4.49 for Prilosec (AC at ¶ 146 & Exhibit A), \$4.14 for Nexium (id.), \$2.91 for Seroquel 100 mg (id.), \$5.48 for Seroquel 200 mg (id.), and \$1.60 for Seroquel 25 mg. Id. Suffolk's particular AstraZeneca allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

#### D. Aventis Pharmaceuticals

1. Suffolk Has Satisfied The Court's and 9(b)'s Requirements For Its Fraud Based Claims Against Aventis Pharmaceuticals

Aventis says that Suffolk does not allege that it purchased the Aventis drug Helixate. Aventis at 2. The statement is wrong. Suffolk alleges that it paid for Helixate in 2001. AC at ¶ 27. Suffolk alleges Helixate had a misleading, false and inflated AWP (id.) of \$1.18 that Aventis reported or caused to be reported. AC at ¶159-160 and Exhibit A. This allegation satisfies 9(b) and this Court's May 13 directive. *In re AWP Litigation*, 263 F. Supp 2d at 194.

# 2. Suffolk's References To Aventis Drugs Anzemet And Taxotere are Appropriate Given Allegations Of General Scheme To Inflate AWPs.

Aventis notes that the County references Anzemet and Taxotere, but does not include them in the list of drugs Suffolk purchased in 2001. Aventis at 2. So what? These two drugs were mentioned in the context of an OIG report revealing that Aventis reports false and inflated AWPs. AC at ¶ 161. Suffolk's reference to this report supports its allegations that Aventis routinely reports misleading price data respecting its covered drugs. To the extent Suffolk paid for Anzemet and Taxotere in past years, Suffolk has been overcharged. AC at ¶ 164.

#### E. Bayer Corporation

1. Suffolk Has Satisfied The Court's And 9(b)'s Requirements For Its Fraud Based Claims Against Bayer

Suffolk alleges that it paid for one Bayer drug, Cipro, in 2001. AC at ¶ 29. Suffolk alleges that Cipro had a misleading, false and inflated AWP (*id.*) of \$5.40 (AC at ¶171 and Exhibit A) that Bayer reported or caused to be reported. *Id.* Suffolk's particular Bayer allegations satisfy 9(b) and this Court's May 13 directive. *In re AWP Litigation*, 263 F. Supp 2d at 194.

#### 2. Bayer's 2001 And 2003 Settlements Do Not Settle Or Release Any Claims Suffolk Might Otherwise Have Against Bayer

Bayer claims that "the State of New York has settled and released any claims plaintiff might otherwise have against Bayer" (Bayer Ind. at 1.) The statement is inaccurate.

Bayer's 2001 Settlement covered AWP price inflation and rebate underpayment for Koate-HP, Kogenate, Konyne-80, and Gamimune from January 1993 through August 1999. (Bayer at 5, and Ex. 1 thereto, 2001 State Settlement Agreement (New York), Part II(C)I-iv.) Thus, to the

entering into this agreement, the United States does not compromise any civil or administrative liability. . . which Bayer may have incurred or may incur as a result of its conduct and its plea of guilty to the attached information." See Bayer, Ex. 2 Plea Agreement, Sec. 9. Accordingly, Suffolk is free under the language of the settlement to sue for Bayer's civil violations that were not precluded by Bayer's agreement with New York State, (i.e. pre-1995 and post-2000 for Cipro and pre-1997 and post-2000 for Adalat) contrary to Bayer's representations. <sup>15</sup>

### F. Berlex Laboratories / Forest Pharmaceuticals, Inc. / Purdue Pharma, L.P., And Reliant Pharmaceuticals, LLC

Suffolk has satisfied the Court's and 9(b)'s particularity requirement for its fraud based claims against Berlex, Forest, Purdue and Reliant. Suffolk alleges that it paid for one Berlex drug, Betaseron, in 2001. AC at ¶30. Suffolk alleges Betaseron had a misleading, false and inflated AWP, (id.) of \$1273.00 that Berlex reported or caused to be reported. AC at ¶183 and Exhibit A. Suffolk's particular Berlex allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

Suffolk alleges that it paid for one Forest drug, Celexa, in 2001. AC at ¶ 35. Suffolk alleges Celexa had a misleading, false and inflated AWP, (id.) of \$2.41 that Forest reported or caused to be reported. AC at ¶213 and Exhibit A Suffolk's particular Forest allegations satisfy 9(b) and this Court's May 13 directive. *In re AWP Litigation*, 263 F. Supp 2d at 194.

Suffolk also asserts claims against Purdue and references in particular its drug, Oxycontin. AC at ¶ 47. Suffolk alleges it had a misleading, false and inflated AWP, (id.) that Purdue

Bayer also challenges Suffolk's standing to sue for damages incurred as a result of Bayer's alleged misconduct. This is not a "defendant-specific" argument. Suffolk's response is set forth at Suffolk opposition Points II and III.

reported or caused to be reported. AC at ¶ 280. While Suffolk did not allege a particular false and inflated AWP for Oxycontin, Suffolk's allegations for Oxycontin and Purdue's complicity in the AWP/Best Price scheme certainly satisfy the pleading standards for those of Suffolk's claims that do not implicate Rule 9(b). *See* Suffolk Opp. at Points II-VI, VIII.

Suffolk alleges that it paid for one Reliant drug, Axid, in 2001. AC at ¶ 48. Suffolk alleges Axid had a misleading, false and inflated AWP, (id.) of \$183.57 that Reliant reported or caused to be reported. AC at ¶ 284, and Exhibit A. Suffolk's particular Reliant allegations satisfy 9(b) and this Court's May 13 directive. *In re AWP Litigation*, 263 F. Supp 2d at 194. 16

#### G. Biogen, Inc.

Biogen says that Suffolk has plead "no particularized factual allegations but simply on a theory of "guilt by association." Biogen Ind. MTD at 1. This is wrong. Suffolk alleges that it paid for one Biogen drug, Avonex, in 2001. AC at ¶ 31. Suffolk alleges Avonex had a misleading, false and inflated AWP, (id.) of \$1076.25 that Biogen reported or caused to be reported. AC at ¶ 189 and Exhibit A. Suffolk's particular Biogen allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

#### H. Eli Lilly and Company

Suffolk has satisfied the court's and 9(b)'s particularity requirement for its fraud based claims against Eli Lilly and Company. Suffolk alleges that it paid for eight Eli Lilly drugs in 2001. AC at 34. Suffolk alleges each had a misleading, false and inflated AWP, (id.) that Lilly reported or caused to be reported. AC at ¶ 208. Specifically, \$3.33 for Prozac 20 mg (AC at ¶ 208

Defendants AMP argument at page 3 is nonsensical. Suffolk alleges that defendants did not comply with their rebate obligations, AC at ¶¶ 361, in order to avoid paying rebates to Medicaid payors such as Suffolk.

and Exhibit A), \$6.66 for Prozac 40 mg (*id.*), \$9.64 for Zyprexa 10 mg (*id.*), \$14.46 for Zyprexa 15 mg (*id.*), \$5.37 for Zyprexa 2.5 mg (*id.*), \$19.25 for Zyprexa 20 mg (*id.*), \$6.34 for Zyprexa 5 mg (*id.*), and \$6.76 for Zyprexa 7.5 mg. *Id.* Suffolk's particular Eli Lilly allegations satisfy 9(b) and this Court's May 13 directive. *In re AWP Litigation*, 263 F. Supp 2d at 194.

#### I. MedImmune, Inc.

Suffolk has satisfied the court's and 9(b)'s particularity requirement for its fraud based claims against MedImmune. Suffolk alleges that it paid for one MedImmune drug, Synagis, in 2001. AC at ¶ 42. Suffolk alleges it had a misleading, false and inflated AWP (id.) of \$1416.48 for Synagis that MedImmune reported or caused to be reported. ¶ 258 and Exhibit A. Suffolk's particular MedImmune allegations satisfy 9(b) and this Court's May 13 directive. *In re AWP Litigation*, 263 F. Supp 2d at 194.

#### J. Merck & Co., Inc.

### 1. Suffolk Has Satisfied The Court's and Rule 9(b)'s Requirements For Its Fraud Based Claims Against Merck

Suffolk alleges that it paid for six Merck drugs in 2002. AC at ¶ 43. Suffolk alleges each had a misleading, false and inflated AWP, (*id.*) that Merck reported or caused to be reported. AC at ¶ 259. Specifically, \$3.04 for Crixivan (AC at ¶ 259 and Exhibit A), \$15.54 for Fosamax (*id.*), \$2.93 for Singulair, (*id.*), \$2.76 of Vioxx (*id.*), \$4.59 for Zocor 20 mg (*id.*), and \$4.59 for Zocor 40 mg, *Id.* Suffolk's particular Merck allegations satisfy 9(b) and this Court's May 13 directive. *In re AWP Litigation*, 263 F. Supp 2d at 194.

### 2. Merck Misrepresents The Basis for Medicaid Reimbursements In New York

Merck tells the Court that the term AWP is "inapplicable to Medicaid." *See* Merck at 5. The statement is false. New York Social Services Law 367-(a)(9) expressly pegs Medicaid reimbursements for certain covered drugs to the AWP for such drugs. Merck's own brief elsewhere acknowledges this. "New York has concluded that [New York's Medicaid Law's reimbursement cost or EAC] equals AWP 'less a percentage discount.' *Id.* at 4. Respectfully, this part of Merck's argument should be withdrawn

#### K. Pfizer Inc. And Agouron Pharmaceuticals, Inc.

Suffolk has satisfied the court's and rule 9(b)'s particularity requirement for its fraud-based claims against Pfizer and Agouron. Suffolk alleges that it paid for fourteen Pfizer and Agouron drugs of different dosages in 2001. AC at ¶ 24, 268. Suffolk alleges each had a misleading, false and inflated AWP, (id.), that Pfizer and Agouron reported or caused to be reported. AC ¶ 133, 268. These drugs and the allegedly false AWP for each are set forth in the chart below. Suffolk's particular Pfizer allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

Drug	Allegedly Fraudulent AWP
GLUCOTROL XL TAB 10 MG	\$0.83
LIPITOR TAB 10 MG	\$2.39
LIPITOR TAB 20 MG	\$3.64
LIPITOR TAB 40 MG	\$3.64
NEURONTIN TAB 300 MG	\$1.39
NEURONTIN TAB 400 MG	\$1.67
NEURONTIN TAB 600 MG	\$2.18
NORVASC TAB 10 MG	\$2.17
NORVASC TAB 5 MG	\$1.50
ZITHROMAX TAB 250 MG	\$7.58
ZOLOFT TAB 100 MG	\$2.65
ZOLOFT TAB 50 MG	\$2.65
ZYRTEC TAB 10 MG	\$210.95
VIRACEPT TAB 250 MG	\$2.52

#### L. Pharmacia Corporation

Suffolk has satisfied the court's and rule 9(b)'s requirements for its fraud based claims against Pharmacia. Suffolk alleges that it paid for three Pharmacia drugs in 2001, Celebrex (200 mg and 100 mg) and Xalatan. AC at ¶ 46. Suffolk alleges each had a misleading, false and inflated AWP, (id.) that Pharmacia reported or caused to be reported. Specifically, \$2.76 for Celebrex 200 mg (¶ 268 and Exhibit A), \$1.58 for Clebrex 100 mg (id.), and \$53.38 for Xalatan.

Id. Suffolk's particular Pharmacia allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

#### M. Sanofi-Synthelabo, Inc.

Suffolk has satisfied the court's and rule 9(b)'s particularity requirement for its fraud-based claims against Sanofi-Synthelabo. Suffolk alleges that it paid for two Sanofi drugs in 2001, Ambien and Plavix. AC at ¶ 49. Suffolk alleges each had false and inflated AWP, (id.), that Sanofi reported or caused to be reported. AC at ¶ 268. Specifically, \$2.69 for Ambien 10 mg, ¶ 268, Exhibit A, \$4.06 for Plavix 75 mg. See AC at Exhibit A. Notably, Sanofi does not deny that it manufactures or markets either drug. In any event, Suffolk's particular Sanofi allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.<sup>17</sup>

#### N. Schering-Plough Corporation

Suffolk has satisfied the court's and rule 9(b)'s requirements for its fraud-based claims against Schering Plough. Suffolk alleges that it paid for one Schering drug, Claritin, in 2001. AC at ¶ 50. Suffolk alleges Claritin had a misleading, false and inflated AWP (id.), of \$92.99 that Schering reported or caused to be reported. AC at ¶ 289 and Exhibit A. Suffolk's particular Schering allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

Sanofi points out that it is not a subsidiary of Pfizer as Suffolk alleged in its complaint. Suffolk will file an appropriate notice of correction. Suffolk also alleges Suffolk's standing to sue for damages it incurred as a result of Sanofi's alleged misconduct. This is not a "defendant-specific argument." See Suffolk Opp. Points II and III.

#### O. TAP Pharmaceutical Products, Inc.

Suffolk has satisfied the court's and rule 9(b)'s particularity requirement for its fraud-based claims against TAP. Suffolk alleges that it paid for two TAP drugs, Prevacid (15mg and 30 mg) in 2001. AC at ¶ 51. Suffolk alleges each had a misleading, false and inflated AWP, (id.) that TAP reported or caused to be reported. AC at ¶ 300. Specifically, \$4.36 for Prevacid 15 mg (AC at ¶ 300 and Exhibit A), and \$4.44 for Prevacid 30 mg. *Id.* Suffolk's particular TAP allegations satisfy 9(b) and this Court's May 13 directive. *In re AWP Litigation*, 263 F. Supp 2d at 194.

#### P. Warrick

### 1. Suffolk Has Satisfied The Court's And Rule 9(b)'s Requirements For Its Fraud-Based Claims Against Warrick

Suffolk alleges that it paid for one Warrick drug, Albuterol, in 2001. AC at ¶ 52. Suffolk alleges Albuterol had a misleading, false and inflated AWP, (id.) of \$21.41 that Warrick reported or caused to be reported. AC at ¶ 306 and Exhibit A. Suffolk's particular Warrick allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

# 2. AWP Claims Are Valid Even When Federal Upper Limits Have Been Set

Warrick says that "reimbursement of drugs for which an FUL has been established is [] not based on AWP" and accordingly "[a]ll AWP claims relating to albuterol during the period when it was subject to a FUL must therefore be dismissed." *See* Warrick at 2. This is incorrect in a number of ways. First, defendants concede that there was no FUL for albuterol for at least part of 2001, (id.) which means that reimbursement was based on AWP-10% at that time. *See* AC at ¶ 73.

Second, even where there is a FUL, reimbursements are made based on AWP because the FUL is calculated based on AWP. *See* 42 C.F.R. 447.332(b). Thus, regardless whether albuterol was subject to FUL or not, its reimbursements were based on its reported false and inflated AWP. <sup>18</sup>

#### Q. Wyeth

Suffolk has satisfied the court's and rule 9(b)'s particularity requirement for its fraud-based claims against Wyeth. Suffolk alleges that it paid for two Wyeth drugs, Effexor and Protonix in 2001. AC at ¶ 53. Suffolk alleges each had a misleading, false and inflated AWP, (id.) that Wyeth reported or caused to be reported. AC at ¶ 311. Specifically, \$1.68 for Effexor, ¶ 311, Exhibit A, and \$3.30 for Protonix 40 mg, Id. Suffolk's particular Wyeth allegations satisfy 9(b) and this Court's May 13 directive. In re AWP Litigation, 263 F. Supp 2d at 194.

Warrick raises a statute of limitations argument. This is not "defendant specific." See Suffolk Opp. Point X.

#### **CONCLUSION**

For all the foregoing reasons, the defendants' motions to dismiss should be denied in their entirety.

Dated: October 30, 2003

New York, New York

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#### **CERTIFICATE OF SERVICE**

I hereby certify that on the 30<sup>th</sup> day of October 2003, I caused a true and correct copy of the County of Suffolk's Opposition To The Defendant-Specific Memoranda In Support of Motion To Dismiss to be served on all counsel of record for defendants by electronic service via Verilaw's Electronic Service System pursuant to Case Management Order No. 2 entered by the honorable Patti B. Saris in MDL No. 1456.

Lloyd M. Donders

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#### **CERTIFICATE OF SERVICE**

I hereby certify that on the 30<sup>th</sup> day of October 2003, I caused a true and correct copy of the County of Suffolk's Opposition To The Defendant-Specific Memoranda In Support of Motion To Dismiss to be served on GlaxoSmithKline, PLC by First Class U.S. Mail and upon defendants on the attached list by Federal Express First Overnight delivery.

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